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IN THE

Supreme Court of the United States

OCTOBER TERM, 1944

No. 316

RALADAM COMPANY, as Claimant of 62 Packages, more or less, of Marmola Prescription Tablets,
Petitioner,

vs.

UNITED STATES OF AMERICA,
Respondent.

REPLY BRIEF IN SUPPORT OF THE PETITION FOR A WRIT OF CERTIORARI IN THE ABOVE CAUSE

ROCKWELL T. GUST,
DAVID A. HOWELL,
Counsel for Petitioner,
1881 National Bank Bldg.,
Detroit 26, Michigan.

Eclipse Composition Company, 243 West Larned St., Detroit

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The Government's brief in opposition furnishes any additional demonstration needed to show that the petition for a writ of certiorari herein is well grounded and should be granted. Finding itself squarely on the horns of a dilemma when it tries to discuss the fundamental issue in the case, *viz*: whether Sec. 502(j) is purely a *labeling* provision *the violation of which* is to be determined *accordingly*, or a provision designed *to do away with self-medication* with *effective* dosages of *useful*

drugs, like desiccated thyroid, because of the potential dangers *inherent* therein, the Government's brief beclouds and evades this issue by a superficial and sophistic treatment of the real basis and effect of the lower Courts' erroneous decisions and the nature of your petitioner's contentions concerning the same.

The reason why the Government finds itself on the horns of a dilemma in this connection is that it must undertake the insurmountable task of convincing this Court, either of the soundness of the manifestly unsound construction placed on Sec. 502(j) by the lower Courts, or that the record herein contains evidence of actual *misbranding* or *mislabeling*, of which it is entirely devoid.

To elaborate: This case was tried and decided by the lower Courts on the fallacious theory that a drug is *misbranded* within the *meaning* of Sec. 502(j) *unless* it can be taken with safety *in violation of* the directions, instructions, and limitations upon its use set forth in its *labeling*. Conversely, the fact that a drug can be taken *according to* its labeling without danger to health—by recognized standards*—was deemed immaterial by the lower Courts in arriving at their decisions.

In other words, the Marmola *labeling*, in recommending the Marmola dosage of desiccated thyroid "*only* as a treatment for *adult* fat persons whose excess fatness is *caused by hypothyroidism* with accompanying subnormal metabolic rates but who are *otherwise normal and healthy*" (R. 8), is concededly *in accord with approved medical practice*.* Nevertheless, the lower Courts found

*See discussion on pp. 2-5 of the petition herein.

Marmola to be *misbranded* under a *labeling* provision, such as Sec. 502(j), because it cannot be taken with safety by persons *other than those for whom* it is recommended and *to whose use* it is *limited* in the Marmola labeling, as aforesaid. This is the only possible interpretation of decisions holding a *properly labeled* drug, by recognized medical standards, *misbranded* because it cannot be taken indiscriminately with impunity by "the public * * * *at large*" (R. 1358), which includes—of necessity—"the strong, the *weak*, the old, the *young*, the well, and the *sick*" (R. 1313).

Therefore, it is again submitted that the decisions of the lower Courts herein are clearly unsound in failing to construe a *misbranding* provision, such as Sec. 502(j), as purely a *labeling* provision *the violation of which* is to be determined *accordingly*—as required by well-settled principles of statutory construction and the decision of this Court in *McDermott v. Wisconsin*, 228 U. S. 115, 133*, in which is was held that "the *label* is the *means of vindication* and the *basis of punishment*" in determining the issue of *misbranding* under a *labeling* provision, such as Sec. 502(j).

Furthermore, the respective decisions of the lower Courts herein are unsound because they are based on a construction of Sec. 502(j) which is *wholly incompatible* with the *continued existence* of *self-medication* with *effective* dosages of *useful* drugs, like desiccated thyroid, contrary to the intention of Congress—the present protestations of the Government throughout its brief to the

*See discussion on pp. 14-15 of the petition herein and on pp. 24-28 of petitioner's initial brief in support thereof.

contrary notwithstanding.* This is so because, as has just been pointed out, this case was tried and decided on the theory that a drug is "dangerous to health" and misbranded within the meaning of Sec. 502(j) unless it is labeled for use *solely* on a doctor's prescription, *or* can be taken with safety *in mistaken violation* of its labeling, *viz.*, by persons *other than those* for whom it is recommended and *to whose use it is expressly limited* in the labeling thereof.

The Government does not contend that a drug is *misbranded* under a *labeling* provision, such as Sec. 502(j), if it is "dangerous to health" when taken in *willful* or *wanton* disregard of directions, instructions, and limitations on it set forth in its labeling. In other words, not even the Government contends that Sec. 502(j) is designed to protect the public from the dangers of self-medication arising out of their own *willful* misconduct, because such dangers are not *inherent* in self-medication, *per se*. However, the Government does contend that a

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*It is *revealing*, to say the least, that, at the same time the Government is so earnestly insisting, *inside* the courthouse, that no such construction has been placed on Sec. 502(j) by the decisions of the lower Courts herein, it is continually insisting, *outside* the courthouse, that such a construction is required of Sec. 502(j), as evidenced by the following excerpts from the public pronouncements of the Federal Food and Drug Administration:

> "You are familiar with the trade notices issued by this administration on August 26 and September 8, 1938, relating to the distribution of preparations containing aminopyrine," etc. "In brief, these notices announced the Administration's opinion that such drugs, if distributed so that they would be used by the general public without *appropriate medical supervision*, would be regarded as *misbranded* in violation of *Section 502(j)* of the Food, Drug, and Cosmetic Act.
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> * * * * *
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> "It should be understood that this principle applies *not only to the specific drugs* which were dealt with in the trade announcements referred to above, *but is applicable to all drugs* which *may be* dangerous to health unless used under *appropriate supervision*" (*Trade Communication No. 4* C. C. H. Food Drug, Cosmetic Law Service, par. 10,160.01, pp. 10,234-35.) [Italics ours.]

(*Continued on next page*)

drug is *misbranded* within the *meaning* of Sec. 502(j), if it is "dangerous to health" when taken in *unwitting* or *mistaken* violation of its *labeling*.

It is the *inherent* dangers of *self-medication*, such as these, with which the lower Courts herein are either expressly or implicitly concerned in their decisions (R. 1313, 1314, 1357-8). They arise from the possibility of a layman untrained in medical science, making an honest mistake in self-diagnosis—as a result of which he gets into difficulty through taking a drug in *mistaken* violation of one or more of the directions, instructions, or limitations upon its use set forth in its labeling.

Clearly, no form of labeling *for self-medication* can be devised to eliminate *such* dangers. By the very nature of things, they are *inherent*, to a varying degree, in *all* self-medication with *effective* dosages of useful drugs, like

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"The administration has received numerous requests from drug manufacturers, retail and wholesale drug associations, and others, for a list of those drug products which it considers dangerous *when sold otherwise than on the prescription of a physician*, dentist, or veterinarian licensed by law to administer drugs.

"* * * Obviously, *it is impossible* to list *all drugs* which *may be* dangerous * * *. As examples of drugs which *are considered dangerous* when distributed for use *otherwise than on prescription*, the following have been mentioned:" [The Food and Drug Administration then proceeds to list some 28 drugs, *including thyroid*, as examples of those which it considers dangerous in *any effective* dosage, "when distributed for use *otherwise* than on prescription."] *(Trade Communication No. 361*, C. C. H. Food Drug Cosmetic Law Service, par. 10,201, p. 10,297.) [Italics ours.]

"The law prohibits the unrestricted sale, within its jurisdiction, of drugs which constitute useful therapeutic agents in the hands of qualified physicians but are too dangerous for use in self-medication. * * * The regulations permit the sale of such drugs on prescription and require the label to bear the legend 'Caution: To be used only by or on the prescription of a physician,' but prohibit general retail distribution of them. * * *" *(Annual Reports of the Food and Drug Administration for 1941-42 and 1942-43.)*

desiccated thyroid;* and, being dangers of self-medication, *per se*, they can only be eliminated by doing away with it entirely—except in dosages which are *ineffective* and, therefore, harmless.

Despite what some people may think of the desirability of such a program from a public health standpoint, the fundamental trouble with it is that the Federal Food, Drug and Cosmetic Act is not designed to accomplish any such result, as fully demonstrated on pages 24-49 of petitioner's initial brief; and, under our system of government, it is beyond the function of the judicial branch to revise legislative enactments, even though it may be felt that the public health or welfare will be better served by so doing.

As has been pointed out on pages 34-37 of petitioner's initial brief, Secs. 502(e) and 502(f) make express provision for the *labeling* of effective dosages of *dessicated thyroid* and other useful drugs *for self-medication*, in spite of the recognized potential dangers *inherent* in their use for such purposes. On pages 38-39 of petitioner's initial brief it is demonstrated that Sec. 502(j) cannot be construed to prevent self-medication with *any dosage* of desiccated thyroid which continues to be available for use on a doctor's prescription.** On pages 40-49 of the same brief, the discussion of the legislative history of the Act clearly reveals that it "is not intended to restrict *in any way* the *availability* of drugs for self-medication" (see page 47 of petitioner's initial brief); and all this clearly contemplates the continuance of self-medication with *effective* dosages of *all* useful drugs, including desiccated thyroid.

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*See discussion on pp. 10-11 of the petition herein and on pp. 29-30 of petitioner's initial brief in support thereof.

**According to the testimony of the Government's own witnesses, the Marmola *dosage* of desiccated thyroid is "widely used" by the medical profession in the treatment of the very same condition for which Marmola is recommended in its labeling. In fact, its use for such purpose is considered "*indispensible* at the present time" (see discussion on pp. 3-4 of the petition herein).

Under these circumstances, it is submitted that the construction placed on Sec. 502(j) by the lower Courts herein is manifestly unsound, because it can have no other effect than to make desiccated thyroid and *all* other useful drugs *unavailable* for *self-medication*, in *effective** dosages. Such a construction is not only contrary to the *intended purpose* of the statute, but will cast grave doubt on its constitutionality, as pointed out on pages 50-8 of petitioner's initial brief. Hence, it is clear that the petition for a writ of certiorari herein should be granted.

Finally, if anything further is needed to demonstrate conclusively the unsound character of the construction placed on Sec. 502(j) by the lower Courts herein, it is the lengthy quotation from a Senate Report forming part of the legislative history of the Act set forth on pages 9-11 of the Government's brief in opposition. For example, in this Senate Report—relied on by the Government to show how Congress intended Sec. 502(j) to be construed—it is stated:

> "There are certain drugs whose employment is *necessary in the treatment of some diseases*, which none the less may in very *exceptional cases* prove *harmful* to persons to whom they are administered. * * *" (Italics ours.)

As has been pointed out in the discussion on pages 3-5 of the petition herein, it is fully established by the Government's witnesses alone that desiccated thyroid is considered by the medical profession to be "necessary in the treatment" of obesity caused or contributed to by, or associated with, hypothyroidism; and, more important still

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*It is conceded by the Government, through the testimony of Dr. Brimmer, Senior Medical Officer of the Federal Food and Drug Administration, that these *same* potential dangers *inherent* in self-medication with the Marmola dosage of desiccated thyroid are *inherent* in self-medication with *any effective dosage* of all *useful* drugs known to *materia medica* (R. 1216, 1236). Other expert witnesses called by the Government testified to the same effect (R. 203-4, 440-1, 712), and none of the Government witnesses testified to the contrary. Also, see discussion on pages 10-11 and 29-30 of petitioner's initial brief.

from the standpoint of whether Marmola is misbranded under Sec. 502(j), desiccated thyroid is "widely used" by the medical profession for such treatment, in the *same average dosage* as that recommended in the Marmola labeling. Likewise, the direction in the Marmola labeling to stop the medication if any unpleasant effects are experienced and then resume at one-half the former dosage after they have disappeared (R. 9) is in accord with approved medical practice (see discussion in second footnote on page 4 of the petition herein).

That self-medication with desiccated thyroid in the Marmola dosage "may in very exceptional cases prove *harmful,*" is conceded. The Marmola labeling expressly advises the prospective consumer of this fact (R. 9). However, this does not render a drug "dangerous to health" within the *meaning* of Sec. 502(j), according to the legislative history of the Act upon which the Government relies as furnishing the key to the correct construction of Sec. 502(j).

The same Senate Report further defines the *intended scope* and *application* of Sec. 502(j) as follows:

> "* * * There are *no useful products* which would be barred from the market under this provision, since *labeling* with *proper directions* for use would *remove* any worth-while article from this ban. * * *
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> "* * * It is not intended that this provision should ban the sale of *useful* drugs of *this kind* when they are *appropriately labeled.* * * *" (Italics ours.)

The Government's proof establishes that desiccated thyroid in the Marmola dosage is not only a "worthwhile" and "*useful* drug" in the treatment of the *sole* condition for which Marmola is recommended, but "indispensable" (R. 902). Moreover, the Government's witnesses have established that its labeling contains "*proper* directions for use," according to *recognized medical*

standards, as has been pointed out on pages 2-5 of the petition herein.

The Government's *only* real claim of *misbranding* under Sec. 502(j) is that Marmola may be "dangerous to health" if a person *unwittingly* takes it *in violation of* the labeled "directions for use" due to a mistake in self-diagnosis.* The trouble with such a claim is that it is clearly immaterial because the Marmola labeling contains "proper directions for use," by *recognized medical standards*, which *removes it* from the "ban" of Sec. 502(j), according to the Senate Report relied on by the Government to show the true meaning and construction thereof.

In view of the foregoing, it is again submitted that this is a case in which this Court should grant the writ of certiorari prayed for, in order to review and correct the patently unsound judgments of the lower Courts herein. It is realized that the Court may not be overly prejudiced

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*It is true that the Government—now that it fully appreciates the fatal deficiencies in its case—also makes a half-hearted attempt to convince this Court, by furnishing a few misleading record references on page 6 of its brief, that Marmola is "dangerous to health," *by recognized medical standards*, when taken *according to* "the directions for use" in its labeling. An analysis of the parts of the record to which the Court's attention is directed by these references further illustrates how devoid the record in this case is of any such proof.

For example, the first of these references (R. 248) directs attention to testimony by the Government's expert, Dr. Newburgh, that: "I know that the dose [of desiccated thyroid] that is *commonly employed, two grains*, will harm *some* individuals." Conceding that this is so, it clearly does not constitute proof that Marmola is harmful to the *only* persons *for whom* it is recommended in its *labeling, viz.*, adult hypothyroid obese persons who are otherwise normal and healthy; and, in addition, the fact that a drug which is properly labeled—by recognized medical standards—"will harm *some* individuals," does not bring it within *the ban* of Sec. 502(j), according to its legislative history relied on by the Government, as disclosing its *intended scope*, which states that "appropriately labeled" drugs are meant to be excluded "from *this ban*," although they occasionally may "prove harmful."

What has just been said regarding the immateriality of Dr. Newburgh's testimony will be found, on examination, to be equally true of the expert testimony of Dr. Boggs (R. 422), Dr. Kurtz (R. 562-5), Dr. Haines (R. 591), Dr. Brussock (R. 638), and Dr. Gunderson (R. 644). Suffice it to

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in favor of continued self-medication with Marmola, and that sometimes "hard cases make bad law," as the old saying goes. However, no precedent has been found for recognizing this saying as a rule of decision in this Court. Congress having passed a statute which "is not intended to restrict *in any way* the *availability* of drugs for self-medication," when they are "appropriately labeled" for such purpose, and Marmola having been established by the testimony of the Government's own witnesses in this case to be "appropriately labeled"—by recognized medical standards—it is clear that the judgment of the lower Courts that Marmola is *misbranded* under Sec. 502(j), regardless of the *propriety* of its *labeling*, has no basis—as a matter of law—and should be reversed.

Respectfully submitted,

ROCKWELL T. GUST AND
DAVID A. HOWELL,
Counsel for Petitioner.

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say that none of the Government witnesses testified, or was asked to testify, that Marmola is "dangerous to health"—*by recognized medical standards*—when taken by the persons *for whom* it is recommended in its *labeling*, according to the other directions and instructions therein set forth. The reason for this is not hard to find. The testimony of these very same witnesses is *all* to the contrary, as has been pointed out on pages 2-5 of the petition herein.

Equally immaterial on the real issues in this case is the testimony of or concerning the lay witnesses, Mrs. Skardarasy (R. 402-4), Mrs. Hansen (R. 444-6), Ophelia Ridgeway (R. 470-3 and 790-2), Florence L. Ruth (R. 652-3), and Estelle Kimoteck (R. 662-3). None of these persons was shown to be one of those *for whom* Marmola is recommended in its labeling, *viz.*, an adult hypothyroid obese person who was otherwise normal and healthy, when she started the medication. Not only did the testimony of some of the witnesses disclose the contrary, but it invariably disclosed that they had violated one or more of the "directions for use," in taking Marmola (see discussion in footnote on p. 6 of the petition herein); and—speaking of "exceptional cases" of harm falling outside the "ban" of the statute—these were the only examples which the Government could produce of alleged harm from *even* the *indiscriminate* use of a product of which more than 20,000,000 packages had been sold over a period of thirty years (R. 18), although the Government advertised extensively for witnesses in medical journals, searched hospital records and interviewed doctors throughout the United States in this connection (R. 756 and 1252-5).